

EXHIBIT A

UNITED STATES
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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
90/019,778	12/13/2024 05:36:23 PM Z ET	-

Title of Invention

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

Application Information

APPLICATION TYPE	Utility / ex parte reexam	PATENT #	11298166
CONFIRMATION #	5684	FILED BY	Jennifer Brinkerhoff
PATENT CENTER #	68362041	FILING DATE	-
CUSTOMER #	27776	FIRST NAMED INVENTOR	Jeff Tyber
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents**TOTAL DOCUMENTS: 8**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
IPR2023-00894 paper 64 Final Written Decision.pdf	68	Other reference-Patent/Application/Search Documents	2209 KB
11298166B2.pdf	32	Copy of patent for which reexamination is requested	3345 KB
20110087227A1.pdf	69	Other reference-Patent/Application/Search Documents	5661 KB
61138920.pdf	98	Other reference-Patent/Application/Search Documents	8539 KB
Fusion sb0081c POA.pdf	2	Power of Attorney	136 KB
Fusion-reexam-request-166.pdf	15	Receipt of Original Ex Parte Reexam fewer than 40 Pages	2243 KB

Rule 1.20(C)(1)

Fusion sb0057.pdf	4	Transmittal of New Application	325 KB
Fusion-IDS.pdf	4	Reexam - Info Disclosure Statement Filed by 3rd Party	98 KB

Digest**DOCUMENT****MESSAGE DIGEST(SHA-512)**

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

U.S. Patent No. 11,298,166

Request for Ex Parte Reexamination

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Fusion Orthopedics, LLC, Requester, v. Extremity Medical, LLC, Patent Owner.	U.S. Patent No.: 11,298,166 Issued: 12 April 2022 Title: <i>Intraosseous Intramedullary Fixation Assembly and Method of Use</i>
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REQUEST FOR EX PARTE REEXAMINATION

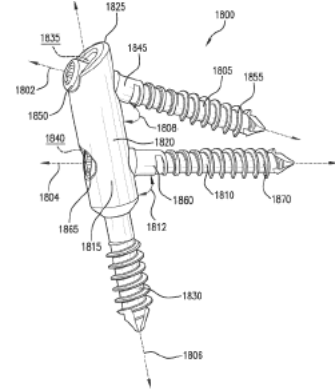
Third Party Requester Fusion Orthopedics, LLC (“Requester”) asks the Office to order reexamination of claims 1–15 of U.S. Patent No. 11,298,166, which issued April 12, 2022 to inventors Jeff Tyber *et al.* (“’166 patent”). The ’166 patent lists on its face assignee Extremity Medical, LLC (“Patent Owner”), though no assignment appears to have been recorded against the ’166 patent. The ’166 patent’s statutory period of enforceability has not yet expired. Substantial new questions of patentability exist and are presented below. Inter partes review of the ’166 patent (IPR2023-00894) recently concluded with a final written decision (“FWD,” copy placed in the image file wrapper of the ’166 patent on Nov. 4, 2024) in which the Patent Trial and Appeal Board (“PTAB”) held all claims except claim 11 unpatentable. FWD 67. The ’166 patent is also the subject of *Extremity Medical, LLC. v. Fusion Orthopedics, LLC*, 2:22-cv-00723-PHX-GMS (D. Ariz.), which is currently stayed.

Requester certifies that the statutory estoppel provisions of 35 U.S.C. §§ 315(e)(1) and 325(e)(1) do not prevent Requester from filing this Request. In particular, the new reference cited (US 2011/0087227 A1 to Mazur) did not come to Requester’s attention until Patent Owner attempted to amend the claims of the ’166 patent during the IPR. The reference was discovered in an updated search commissioned during the IPR that was specifically focused on the new limitation Patent Owner added to the claims in its Revised Motion to Amend. Patent Owner’s amendment was unsuccessful, because the PTAB found the proposed claims anticipated by Mazur. FWD 63.

Mazur anticipates the patented claims for exactly the same reasons the PTAB found that it anticipates the proposed amended claims. Because the patented claims are not patentably distinct from the proposed claims the PTAB finally refused, Patent Owner is barred from defending the patented claims. 37 C.F.R. § 42.73(d)(3)(i).

I. Background and Summary of the '166 patent

The '166 patent issued from application serial no. 17/323,923, which was filed May 18, 2021 and claims an earliest effective filing date of its claimed subject matter through a series of continuations and a division to application serial no. 12/658,680, filed Feb. 11, 2010, now U.S. Patent No. 9,044,282. The '166 patent also claims the benefit of earlier applications which lack disclosure of the claimed subject matter. The '166 patent concerns orthopedic implant devices, such as intramedullary nails, that are used to repair or reconstruct hand and foot bones. (col. 1, ll. 28–33). The claims are directed to bone fusion assemblies, which (as shown in Figure 18) include third member 1815 spanned by identical first (1805) and second (1810) members, both of which have a self-tapping edge for removing bone material. FWD 5–7.



The Final Written Decision in IPR2023-00894 is filed with this Request for the Examiner's convenience. It is not being relied on for any argument of unpatentability. It is cited merely as a record of prior action taken by the Office that is binding on Patent Owner and on all further proceedings concerning the '166 patent. All arguments relied upon in this Request are contained within the four corners of the Request itself and not in the Final Written Decision. Therefore, the Request satisfies the streamlined page limit. The Director is authorized to charge any fee deficiency to the deposit account listed on the transmittal if the Request is deemed non-compliant with the streamlined requirements.

IV. Detailed Explanation of Substantial New Questions of Patentability

A. Mazur anticipates claims 1–15

1. Patent Owner is estopped from defending patentability over Mazur.

During IPR2023-00894, Patent Owner submitted proposed substitute claims 16–30 which corresponded to patented claims 1–15, respectively, and narrowed the patented claims by adding a limitation concerning the geometry of the recited first aperture. FWD 50. The proposed substitute claims only narrowed the patented claims and did not enlarge them in any way. FWD 47. The patented claims therefore are generic to their proposed substitute counterparts and, consequently, not patentably distinct from them.

The PTAB found that Mazur anticipated each of proposed substitute claims 16–25 and 27–30 and therefore *denied* Patent Owner's Revised Motion to Amend Claims. FWD 49, 63, 66–67. The PTAB did not reach claim 26 because its corresponding patented claim 11 was not found unpatentable. FWD 66.

The PTAB's decision to deny Patent Owner's Revised Motion to Amend Claims constitutes a final refusal of proposed substitute claims 16–25 and 27–30, because the PTAB rendered its refusal in its Final Written Decision in IPR2023-00894 and after Patent Owner fully participated in briefing, expert discovery, and oral argument. FWD 1–3 (describing procedural history of IPR2023-00894). Patent Owner therefore is estopped from taking any position inconsistent with the PTAB's determination that proposed substitute claims 16–25 and 27–30 are anticipated by Mazur. 37 C.F.R. § 42.73(d)(3)(i) (“A patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent: (i) A claim that is not patentably distinct from a finally refused or canceled claim”).

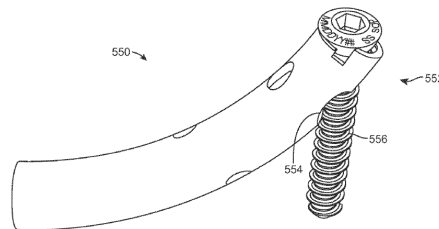
This means that Patent Owner cannot defend the patentability of claims 1–10 and 12–15 over Mazur, because these claims are generic to claims that the PTAB finally refused. A claim that is generic to a claim found unpatentable over prior art is itself unpatentable over that same art.

Patent Owner also is precluded from defending the patentability of claim 11 because it is patentably indistinct from claim 10, which the PTAB found unpatentable in the Final Written Decision for IPR2023-00894. FWD 65, 67. Claim 11 is not patentably distinct from claim 10 because it merely duplicates structure (the “self-tapping edge for removing bone material”) already recited in claim 10. *In re Harza*, 274 F.2d 669, 671 (CCPA 1960) (“It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced”); M.P.E.P. § 2144.04(VI)(B). In this case, the only difference between claim 11 and unpatentable claim 10 is the duplication of the “self-tapping edge for removing bone material,” which has “no patentable significance” as explained in *Harza*. Patent Owner admitted that screws 1805 and 1810 are duplicates of one another (’166 patent, 13:26–31) and has made no argument about a “new and unexpected result” from duplicating this structure. Patent Owner therefore is estopped from defending the patentability of claim 11.

2. *Substantial New Question of Patentability*

Mazur US 2011/0087227 A1 was filed Dec. 18, 2009 and claims the benefit of provisional application Ser. No. 61/138,920 filed Dec. 18, 2008 containing near-identical specification and drawings. Mazur is effective prior art as of its provisional date because claim 1 of Mazur is fully supported by its provisional application, as shown below.

Mazur discloses a bone fixation device having a hub 550 with a series of holes through which screws e.g. 556 pass to anchor the hub in bone. Figure 16A shows the hub and one screw that passes in through the end of the hub and out through hole 554, while another screw may pass through the more distal set of holes:



Mazur, Fig. 16A

Although Figure 16A shows a curved hub, Mazur discloses that the hub may instead be “straight.” Mazur ¶ [0094]; FWD 54:20-55:17; 59:8-23; 62:3-7. Additionally, Mazur emphasizes interchangeability of parts. Mazur, Abstract and ¶¶ [0060], [0088]. An example of a straight hub is shown in Figure 7:

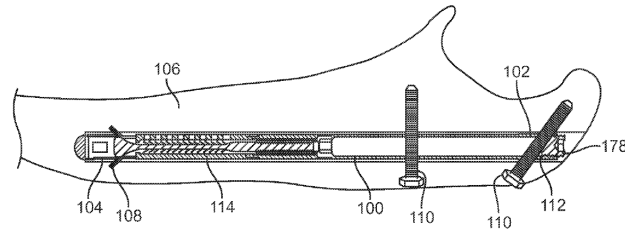


FIG. 7

The resulting embodiment has a first screw passing through the notched open end of a straight hub, and a second screw passing through another pair of apertures at an angle substantially perpendicular to the straight hub, as shown for screw 110 in Figure 7.

Mazur also indicates unambiguously that the straight hub is applicable to the Figs. 16A–E embodiment, because Figs. 16A–E show the same embodiment as Figs. 11 and 12. Mazur discloses that Figs. 12G–I “show details of a curved hub 400 similar to hub 302 illustrated in FIGS. 11A–D.” Mazur ¶ [0096]. Mazur also discloses that Figs. 12A–20B (including 16A–E) show “further examples” of the hubs described in Figs. 11A–D. Mazur ¶ [0095]. Consequently, Figs. 16A–E are describing a curved hub as shown in Figs. 11A–D. FWD 59:24- 60:8. Inspection of drawings from each figure group immediately demonstrates that they are showing identical or similar hubs:

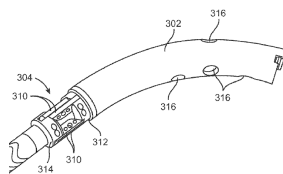


Fig. 11A (detail)

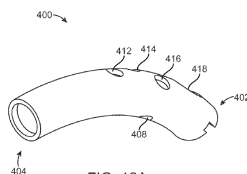


Fig. 12A (detail)

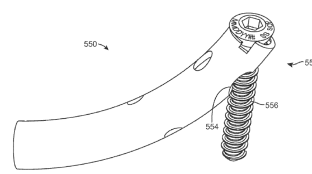
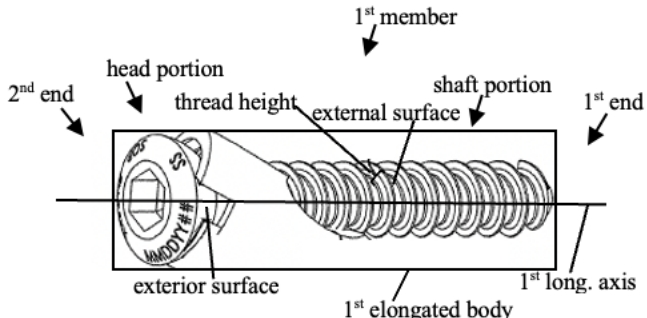


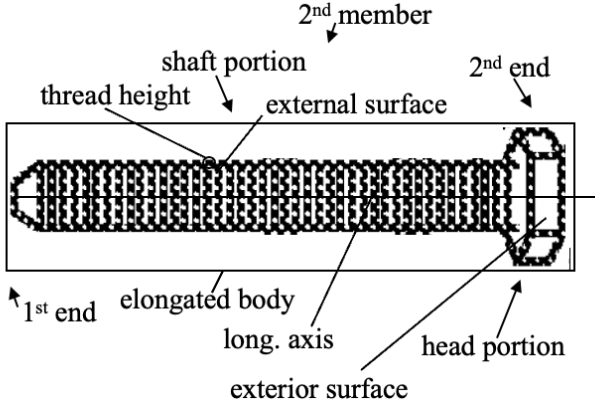
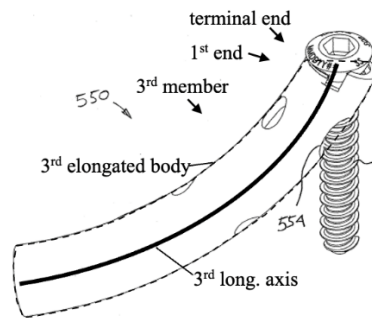
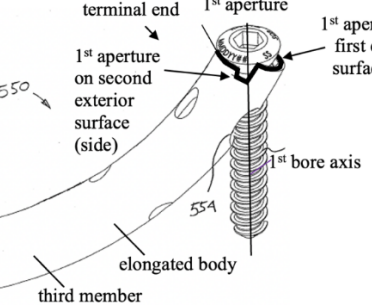
Fig. 16A (detail)

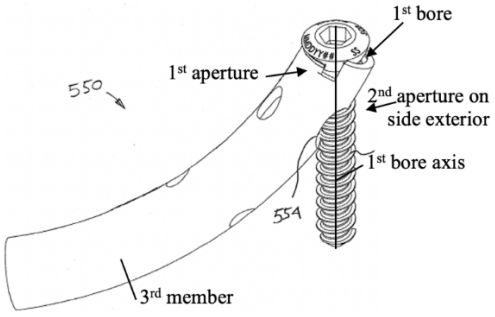
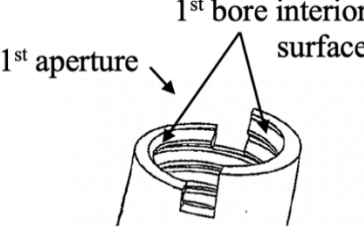
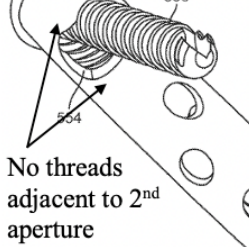
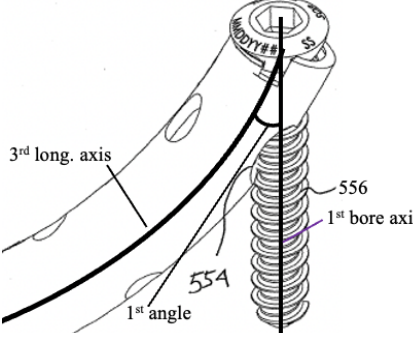
Mazur even indicates when parts are *not* combinable, *e.g.*: “either screw 422 or 424 . . . but not both at the same time,” Mazur ¶ [0099], thus underscoring the significance of occasions when Mazur points out interchangeability. For these reasons, the disclosure in Mazur paragraph [0094] indicates that the straight hub is applicable to Figs. 16A-16E.

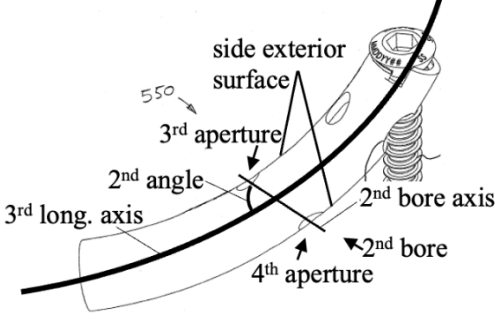
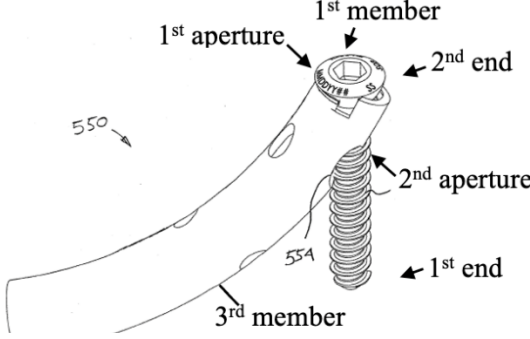
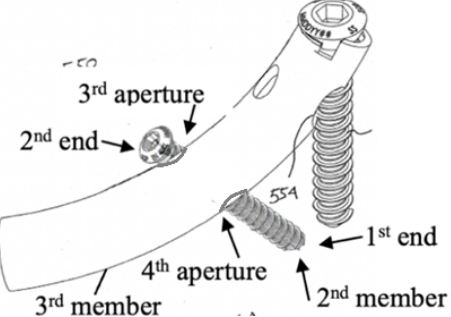
As shown in the following table, Mazur anticipates claims 1–15 either expressly as shown and described for Figure 16A or by disclosure elsewhere in the application that is

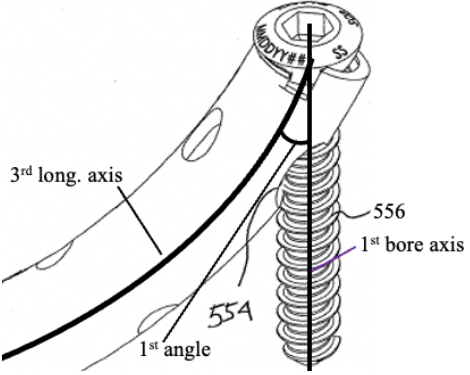
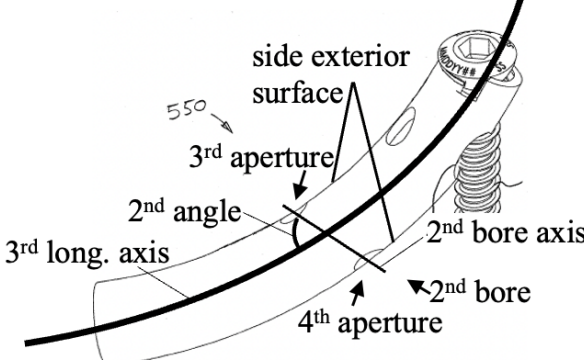
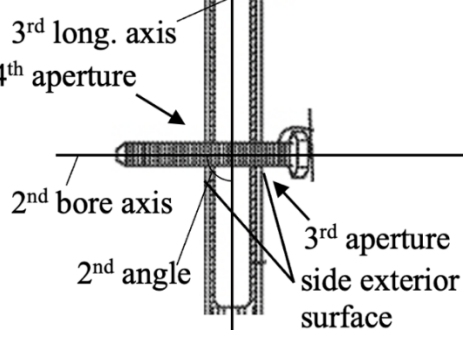
applicable to the various hub embodiments. FWD 48:11-14. Dependent claims reciting similar features are grouped for brevity. Patent Owner did not contest any limitation of the proposed amendment to claim 1 except for the added limitation specifying geometry of the first aperture and the “straight line” nature of the third longitudinal axis, and the PTAB rejected Patent Owner’s argument concerning those limitations. FWD 49–62.

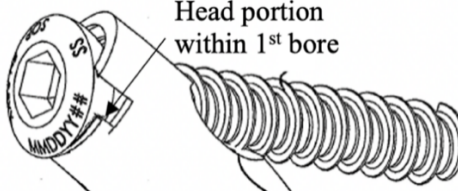
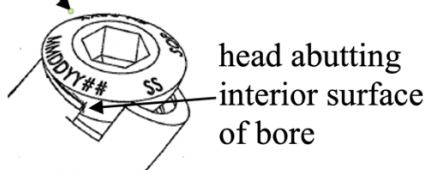
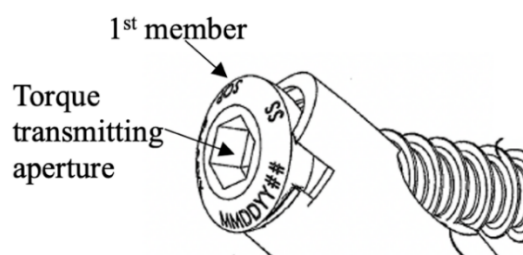
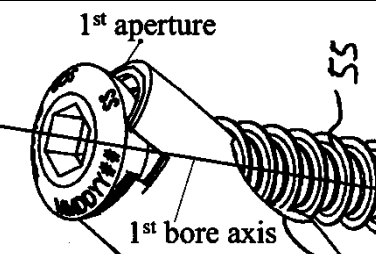
Claim	Limitation	Mazur; <i>Mazur provisional</i> (where different)
1a/12a	1. An assembly for bone fusion, comprising:	[0011] “bone fixation device” The PTAB adopted this argument (FWD 49:9-11)
1b/12b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	 <p>Fig. 16A detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>

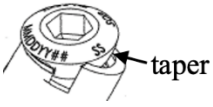
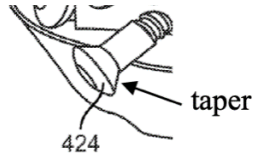
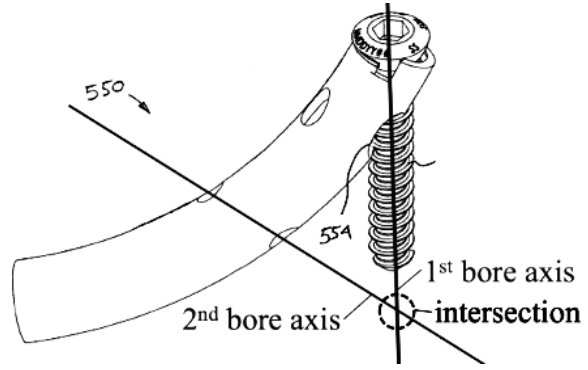
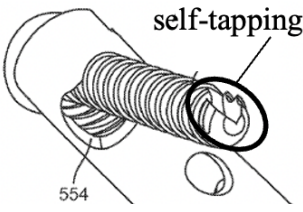
1c/12c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	 <p>Fig. 7 detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
1d/12d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,	 <p>Fig. 16A (annotated) [0094] ([0093] in prov.) “Further, a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations.” The PTAB adopted this argument (FWD 54:20-55:17; 58:18-62:7)</p>
1e/12e	wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body,	 <p>Fig. 16A annotated) The PTAB adopted this argument (FWD 52:16-53:12)</p>

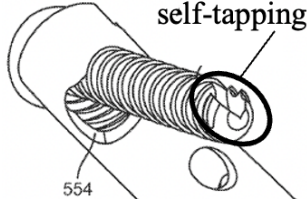
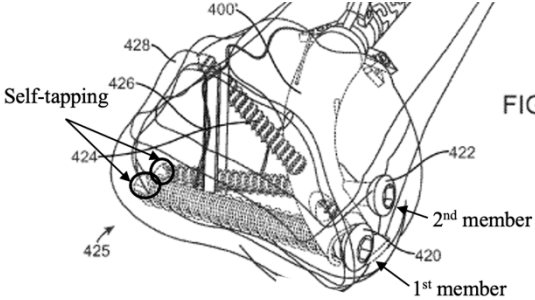
1f/12f	and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member,	 <p>Fig. 16A (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>
1g/12g	wherein the first bore comprises an interior surface at the first aperture ₁	 <p>Fig. 13A detail (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>
1h/12h	wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and	 <p>Fig. 16B detail (annotated)</p> <p>No threads adjacent to 2nd aperture</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>
1i/12i	wherein the third longitudinal axis and the first bore axis define a first angle,	 <p>Fig. 16A (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>

1j/12j	<p>wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,</p>	 <p>Fig. 16A (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
1k/12k	<p>wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,</p>	 <p>Fig. 16A (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
1l/12l	<p>wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,</p>	 <p>Fig. 16A (annotated) – adapted to include a second member added to the figure as implied by the holes in the third member and described for other figures, such as Fig. 7. The PTAB adopted this argument (FWD 49:9-11)</p>

<p>1m (this limitation is omitted from claim 12)</p>	<p>wherein the first angle is in the range of about 0 degrees to about 90 degrees,</p>	 <p>Fig. 16A (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11; 54:20-55:17; 58:18-62:7)</p>
<p>1n/12n</p>	<p>wherein the second angle is in the range of about 0 degrees to about 90 degrees, and</p>	 <p>Fig. 16A (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11; 54:20-55:17; 58:18-62:7)</p>
<p>1o/12o</p>	<p>wherein the second bore axis is substantially perpendicular to the third longitudinal axis.</p>	 <p>Fig. 7 (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11; 54:20-55:17; 58:18-62:7)</p>

	Claim 2, 6, and 13	
2/6/13	The assembly of claim 1/5/12, wherein the head portion of the first member resides at least partially within the first bore.	 <p>Head portion within 1st bore</p> <p>Fig. 16A detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
	Claim 3 & 7	
3/7	The assembly of claim 2/6, wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.	 <p>1st aperture</p> <p>head abutting interior surface of bore</p> <p>Fig. 16A detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
	Claim 4	
4	The assembly of claim 3, wherein the head portion of the first member comprises a torque transmitting aperture.	 <p>1st member</p> <p>Torque transmitting aperture</p> <p>Fig. 16A detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>
	Claim 5	
5	The assembly of claim 1, wherein the first aperture of the third member is aligned on the first bore axis.	 <p>1st aperture</p> <p>1st bore axis</p> <p>Fig. 16A detail (annotated) The PTAB adopted this argument (FWD 49:9-11)</p>

	Claim 8, 14, & 15	
8/14/15	The assembly of claim 1/13/12, wherein the head portion of the first member is tapered.	  <p>Fig. 16A detail (annotated) Fig. 12G detail (annotated)</p> <p>[0079] ([0081] in provisional) “The heads of screws 110 may be configured to be self-countersinking”</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>
	Claim 9	
9	The assembly of claim 1, wherein the first bore axis and the second bore axis intersect outside the third member.	 <p>Fig. 16A (annotated)</p> <p>The PTAB adopted this argument (FWD 62:8-63:9)</p>
	Claim 10	
10	The assembly of claim 1, wherein the first end of the first member includes a self-tapping edge for removing bone material.	 <p>Fig. 16B detail (annotated)</p> <p>The PTAB adopted this argument (FWD 49:9-11)</p>

	Claim 11	
11	The assembly of claim 10, wherein the first end of the second member includes a self-tapping edge for removing bone material.	 <p>Fig. 16B detail (annotated)</p> <p>The second member is another instance of the first member and thus would include all of the properties of the first member.</p> <p>[0097] ([00096] in provisional) “holes 408 and 414 are aligned to receive a second bone screw”</p>  <p>FIG. 12H</p>

Mazur is entitled to its provisional filing date because Mazur’s provisional application supports at least Mazur published claim 1, as follows:

Mazur p. 11	Mazur provisional
1. An implantable bone fixation device comprising:	[0011] “a bone fixation device”
an elongate body having a flexible state and a rigid state;	[0069] “body portion 114 changes from being flexible to rigid”
a rigid hub connected to a proximal end of the elongated body,	[0012] “a hub located on a proximal end of the elongated body” [0093] “a straight, curved, flexible, rigid, or no hub at all may be used”
the hub having an array of pilot holes over a portion of an outer surface,	[0116] “Slots 702 permit in vivo screw hole formation by acting as long pilot holes for drill bits or bone screws.”

each of the pilot holes being configured to expand upon receipt of a fastener therethrough; and	[0116] “A bone screw tip may be inserted into one of the slots 702 without pre-drilling. Upon insertion, the slot and surrounding slots will deform to make way for the screw”
an actuator operably connected to the elongate body for changing the body from the flexible state to the rigid state.	[0069] “continued rotation of actuator 126 draws the proximal end 102 and the distal end 104 of device 100 closer together until cuts 116 are substantially closed. As this happens, body portion 114 changes from being flexible to rigid”

Mazur’s provisional application therefore satisfies the requirements to serve as prior art against the claims of the ’166 patent because it (a) discloses all the limitations relied upon as prior art for showing anticipation of each ’166 patent claim, and (b) supports at least one claim of Mazur’s nonprovisional application. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1380–81 (Fed. Cir. 2015).

B. Mazur renders obvious claims 1–15

The PTAB also found that Mazur renders obvious proposed claims 16–25 and 27–30. FWD 57–63. This finding is binding on Patent Owner and estops it from arguing for patentability of claims 1–15 for the reasons given above, namely, that the patented claims are all generic to their proposed counterparts and therefore lack patentable distinctiveness over them.

Claims 1–15 are unpatentable for obviousness over Mazur because Mazur expressly suggests interchangeability of its parts, which would have led a person having ordinary skill in the art (“POSA”) to the subject matter encompassed by the claims. The portions of Mazur disclosing that features of one embodiment apply to others, in particular the statement in Mazur paragraph [0094] (prov. [0093]) that “a straight, curved, flexible, rigid, or no hub at all may be used with the above combinations,” also suggest to the POSA to modify the embodiment shown in Figure 16A to have a straight hub. Mazur’s extensive description of straight-hubbed embodiments show how to implement such an embodiment with a reasonable expectation of success. Mazur discloses all the remaining embodiments

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of the proposed claims in the manner discussed above. For these reasons, a POSA would have found it obvious from Mazur to reach the subject matter of every proposed claim.

Claim 11 further limits claim 10 requiring that the second member include a self-tapping edge for removing bone material. Claim 10 requires exactly the same structure on the *first* member. Thus, the only difference between claim 11 and claim 10 is the duplication of the self-tapping edge. In other words, claim 10 requires that the first member have a self-tapping edge, and claim 11 requires that both the first and second members have self-tapping edges. Patent Owner admitted that the first and second members (screws 1805 and 1810) are duplicates of one another ('166 patent, 13:26–31).

But it has long been recognized that the mere duplication of structure does not confer patentability on otherwise unpatentable subject matter, absent a showing of an unexpected result produced by the duplication. *In re Harza*, 274 F.2d 669, 671 (CCPA 1960) (“It is well settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced”); M.P.E.P. § 2144.04(VI)(B).

Claim 11 therefore is not patentably distinct from claim 10, because Patent Owner merely duplicated structure from claim 10 without showing that the duplicate results in some unexpected benefit. Claim 11 is consequently obvious over Mazur for the same reasons as claim 10. Furthermore, Patent Owner is estopped from defending or maintaining claim 11 because it is patentably indistinct from a claim the PTAB finally determined to be unpatentable, namely, claim 10. 37 C.F.R. § 42.73(d)(3)(i).

V. Conclusion

Requester therefore asks that the Office reexamine Claims 1–15 of the '166 patent.

Respectfully submitted,

Dated: December 13, 2024

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Certificate of Service: I certify that this Request for Ex Parte Reexamination and all other documents accompanying this Request were served by First Class Mail to the correspondence address of record: “27776 - Kelley Drye & Warren LLP, One Jefferson Road, Parsippany, NJ 07053” on December 13, 2024.

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